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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,842	11/13/2001	Eliezer Masliah	6627-PA9013	7702
25225	7590	05/16/2006	EXAMINER	
MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			STANDLEY, STEVEN H	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/806,842	Applicant(s) MASLIAH ET AL.	
	Examiner Steven H. Standley	Art Unit 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16,17,21-25,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27 is/are allowed.
- 6) ☒ Claim(s) 16-17, 21-25, 27-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment filed 2/17/06 has been made of record. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### **Objections/Rejections: Withdrawn**

#### ***Claim Objections***

2. Objection to claim 16 is withdrawn due to applicant's amendment.

#### ***Claim Rejections - 35 USC § 102***

3. Rejection of claims 16, 21-25, and 27 over Biere et al under 35 USC § 102(e) is withdrawn due to applicant's amendments.

#### ***Claim Rejections - 35 USC § 103***

4. Rejection of claim 16-17, 21-25, and 28 under 35 USC § 103(a) over Jensen et al and further view of Jenner et al. is withdrawn due to applicant's amendment. Applicant is correct in asserting that Jensen et al does not teach aggregation of NACP. Therefore, the rejection over Jensen in further view of Jenner et al is withdrawn. Furthermore, the prior art teaches localization of synuclein to amyloid plaques, binding of synuclein to a-beta, and aggregation *with* a-beta, but does not teach synuclein aggregation stimulated by exogenous iron per se or measuring synuclein aggregation after stimulation with iron.

**Objections/Rejections: Maintained/New Grounds*****Claim Rejections - 35 USC § 112***

5. Rejection of claims 16-17, 21-25, and 28 under 35 USC § 112, 1<sup>st</sup> paragraph, enablement is maintained for the reasons made of record in the office action dated 11/15/05. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues that the invention is not "best scientific practice." However, the specification does not teach any reasonable manner of the assay of the present claims using an experimental and control sample from different origins, and further does not specify the breadth of where the samples could be derived from, nor what the samples could contain in addition to NACP/Synuclein. The only limitation on each sample is that they 'comprise NACP/Synuclein.' Otherwise there is no requirement for them to contain the same amount of NACP/Synuclein, that the synuclein have the same sequence, or that any number of characterized and unknown factors that bind or otherwise interact with NACP/Synuclein. For instance, the control or test sample could contain an iron chelator or binder such as transferrin, an endogenous inhibitor of aggregation, a difference in the level of endogenous free radical scavengers, or any number of other differences that would render the results meaningless.

Amendment of claim 16 to incorporate all of the limitations of claim 27 and subsequent cancellation of claim 27 would be remedial.

### Conclusion

Claims 16-28 are free of the prior art. Amendment of claim 16 to incorporate all the limitations of claim 27 and cancellation of claim 27 would render the claims allowable.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Guptasarma et al (1992) teaches that **oxidation** of a generic polypeptide is obvious to do via hydroxyl radicals generated from the fenton reaction, which in the instant application is accomplished through  $FE^{2+}$  donating an electron to  $H_2O_2$ , but also indicates that the types of amino acids that are oxidized varies with different metal catalyzed reactions (see page 4301, right col). Thus, while it is obvious to oxidize a generic polypeptide by generating hydroxyl radicals, it is not obvious that the oxidation will cause cross-linking and thereby aggregation.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.

5/09/06



  
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